Individual Safety Report

3549328-8-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNeil Consumer Healthcare

McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

Page ____ of ____

Approved by FDA on 11/15/93

Mfr report #

UF/Diet report #

FDA use only

A Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	55 yrs or Date of birth:	( )female (X)male	unk lbs or kgs

B Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)
( ) life-threatening
( ) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
(x) other: recovered

3. Date of event	4. Date of this report
5/30/1999 (mo/day/yr)	10/13/99 (mo/day/yr)

5. Describe event or problem

Consumer alleges that the use of an Extra Strength TYLENOL® acetaminophen product was associated w/SOMNOLENCE (groggy), SYNCOPE (fainted) & LIVER FUNCTION TESTS ABNORMAL. Consumer indicates he was on vacation when he began to experience a toothache on 5/25/99. Addl info was rec'd on 2/2/2000. Med rec indicate pt developed a toothache in his left lower jaw for which he consulted a dentist. Dentist prescribed PERCOCET® & TYLENOL®. Pt presented to ED on 5/30/99 w/complaints of MALAISE, NAUSEA & DIZZINESS. According to pt, he took at least 20 PERCOCET® & about 55 Extra Strength TYLENOL over the course of 5-6 days (OVERDOSE). Pt could not be exact about how much TYLENOL he took. In ER, an acetaminophen level was taken. MD did not rule out possibility of acetaminophen toxicity. MUCOMYST® therapy was advised to pt, but pt refused. Pt refused to be admitted to hospital & wanted to f/u w/his physician. Case was discussed with Poison Control Center who noted that pt deserved at least 24 hr observation & 24 hr MUCOMYST® therapy. Pt signed out from ER AMA.

6. Relevant tests/laboratory data, including dates

5/30/99 (In ER): serum acetaminophen level (at unspecified time)=less than 5 ug/ml, AST=96, ALT=119, GGT=33, Alb=4.3, total bili=1.3, AP=120, BP=168/84, HR=55, RR=24, T=36.2, pulse O2 (room air)=94%, WBC=6.8, Hgb=16.5 (See Sect B7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

hypothyroidism, hypertension, bipolar disorder, history of triple A repair, and denies alcohol use; NKDA

Sect B6 cont: Hct=46.9, PLT=269, UA: PRO=15, GLU=normal, KET=neg, blood=neg; GLU=96, BUN=26, SCr=1.5, Na=139, K=4.9, Cl=109, CO2=22.9, and hyperlipidemia noted in blood

C Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL product
#2 PERCOCET®

2. Dose, frequency & route used

#1 about 27.5 grams, po
#2 at least 20 tablets, po

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 5/1999; over 5-6 days
#2 5/1999; over 5-6 days

4. Diagnosis for use (indication)

#1 toothache pain
#2 toothache pain

5. Event abated after use stopped or dose reduced

#1 (X) Yes ( ) No ( ) N/A
#2 (X) Yes ( ) No ( ) N/A

6. Lot # (if known)	7. Exp. date (if known)
#1 unknown	#1 unknown
#2 unknown	#2 unknown

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

SYNTHROID®, SULAR®, lithium, aspirin, ZOLOFT®, and antibiotics

G All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-273-7303

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
(x) consumer
( ) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr): 10/13/99

5. (A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day ( )15-day
( ) 10-day (X)periodic
(X) Initial ( )follow-up #

8. Adverse event term(s)

SOMNOLENCE
SYNCOPE
LIVER FUNC ABNO
MALAISE
NAUSEA
DIZZINESS
OVERDOSE

9. Mfr. report number: 1252394A

E Initial reporter

1. Name, address & phone #

[redacted], MD
[redacted] Hospital Emergency Department
PO Box [redacted]
[redacted]

AUG - 9 2000

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk

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FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.